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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/868,744	01/09/2002	Frank Schepers	Lettuce	6532

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EXAMINER	
MEHTA, ASHWIN D	

ART UNIT	PAPER NUMBER
1638	

DATE MAILED: 07/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/868,744	SCHEPERS ET AL.	
	Examiner	Art Unit	
	Ashwin Mehta	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 May 2005*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-7,9-14,16 and 18-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-7,9-14 and 18-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *09 January 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on May 12, 2005 has been entered.

2. The objection to claim 9 is withdrawn, in light of the claim amendments

3. The rejection of claims 9-14 and 16-21 under 35 U.S.C. 112, second paragraph, is withdrawn in light of the claim amendments.

Claim Objections

4. Claims 9-14 and 18-21 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Regarding claim 9, and those dependent thereon: the claim indicates that "at least some of said plant cells" of the plant produced by the method of claim 1 comprise the construct. However, claim 1 indicates that the plant stably expresses the RNA, and that the method is for

producing stable transgenic expression. If the expression is to be stable, then the plants are stably transformed, not transiently transformed. All cells of the plants produced by the method of claim 1 would comprise the DNA construct.

Claim Rejections - 35 USC § 112

5. Claims 1, 3-7, 9-14, 16, and 18-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1: the recitations, "stable transgenic expression" in line 1 and "stably expressed" in line 6 render the claim indefinite. In the context used, "stable" and "stably" are relative terms, with no definite meaning. What can be considered as "stable" expression to one may not be considered stable to another.

In claims 9-14 and 18-21: claims are directed to a plant formed by the method of claim 1. However, it is unclear whether this plant is that into which the DNA construct is introduced, or the progeny of that plant.

In claim 10: the recitation, "wherein RNA produces" renders the claim indefinite. It is unclear whether or not this RNA is the same as the RNA mentioned in claim 1. It is suggested that the term, --said-- be inserted in line 1 before "RNA".

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1, 3-7, 9-14, 16, and 18-21 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are broadly drawn towards a method of producing stable transgenic expression in a genetically modified lettuce or sunflower plant, comprising transforming said plant with a DNA construct for expressing an RNA under the Arabidopsis thaliana ACT2 promoter, wherein the RNA is stably expressed in the progeny of the plant; or wherein the promoter has the sequence shown in SEQ ID NO: 1; or wherein the RNA codes for a heterologous or homologous protein; or wherein the RNA inhibits production of a homologous protein or is antisense to DNA coding for said homologous protein; or any genetically-modified Compositae plant produced by said method; or said method wherein the DNA construct comprises the gus gene or the oxox gene.

Page 2, lines 20-27 of the specification indicates that a method is provided for producing a genetically-modified Compositae plant comprising transforming the plant with a DNA construct to express RNA under the control of the ACT2 gene promoter. Pages 6-8 of the specification discuss the production of lettuce plants into which were introduced a DNA construct comprising the A. thaliana ACT2 gene promoter operably linked to the GUS coding sequence. Progeny of the transformants were also produced, in which GUS expression was observed.

However, the specification does not describe a method for "stable transgenic expression" or a method in which RNA is "stably" expressed. There is no written description support for "stable" expression or "stably" expressed. This is a NEW MATTER rejection.

Claim Rejections - 35 USC § 103

7. Claims 1, 3-7, 9-14, 16, and 18-21 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Curtis et al. (J. Exp. Bot., 1994, Vol. 45, pages 1441-1449) or Grayburn et al. (Plant Cell Rep., 1995, Vol. 14, pages 285-289) in combination with An et al. (Plant J., 1996, Vol. 10, pages 1078-121), Hartman et al. (WO 92/14824), Bernasconi et al. (U.S. Patent No. 5,633,437), and Bidney et al. (U.S. Patent No. 6,084,164), for the reasons of record stated in the previous Office actions. Applicants traverse the rejection in the paper filed May 12, 2005. Applicants' arguments have been fully considered but were not found persuasive.

The claims are broadly drawn towards a method of producing stable transgenic expression in a genetically modified lettuce or sunflower plant, comprising transforming said plant with a DNA construct for expressing an RNA under the Arabidopsis thaliana ACT2 promoter, wherein the RNA is stably expressed in the progeny of the plant; or wherein the promoter has the sequence shown in SEQ ID NO: 1; or wherein the RNA codes for a heterologous or homologous protein; or wherein the RNA inhibits production of a homologous protein or is antisense to DNA coding for said homologous protein; or any genetically-modified Compositae plant produced by said method.

Curtis et al. teach a method for transforming lettuce. The transformation vector introduced into the transgenic lettuce plants included the GUS gene (pages 1443-1448).

Curtis et al. do not teach transgenic sunflower plants, an act2 gene promoter, a herbicide tolerance gene, the oxox gene, or genes encoding RNA that inhibit the production of a homologous protein.

Grayburn et al. teach a method for transforming sunflower (pages 287-289).

An et al. teach the Arabidopsis ACT2 promoter, and transgenic plants transformed with a vector comprising the ACT2 promoter operably linked to the GUS coding sequence, that the ACT2 promoter is active in most organs, and assert that that the ACT2 5'region is ideal for directing high-level expression of various transgenes in plants (pages 108-113, 117).

Hartman et al. teach methods for producing transgenic plants, including sunflower, transformed with a vector comprising the oxalate oxidase (oxox) gene, to confer resistance to sclerotinia (page 2, line 3 to page 8, line 26; page 27, line 25 to page 28, line 11; page 29, line 15 to page 32, line 22).

Bernasconi et al. teach transgenic plants with increased resistance to acetolactate synthase (ALS) inhibition by ALS herbicides, conferred by a gene encoding ALS (col. 5, line 65 to col. 6, line 12; col. 8, line 1 to col. 10, line 67; claims).

Bidney et al. teach transgenic sunflower plants expressing RNA that is antisense to the transcript of stearoyl-ACP desaturase and increase the stearate content of sunflower oil, which decreases the amount of processing to produce margarine, makes it less resistant to oxidation to make it more useful in the production of soaps an the coating of foods (col. 1, line 24 to col. 2, line 27; col. 9, line 46 to col. 12, line 53).

It would have been obvious and within the scope of one of ordinary skill in the art at the time the invention was made to modify the method of producing transformed lettuce or

sunflower plants of Curtis et al. or Grayburn et al. by replacing the promoter on the transformation vectors with any other promoter desired, including the act2 gene promoter taught by An et al. One would have been motivated to use different promoters, including the act2 promoter, depending on one's desired end. One would have been motivated to use the act2 promoter, given the assertion by An et al. that is would be ideal for directing high-level expression of transgenes in plants. It was obvious that stable RNA expression was obtained with the act2 promoter, given the high level of expression and activity in various plant organs, as demonstrated by An et al. It would also have been obvious to introduce any gene of interest linked to the act2 promoter, whether heterologous or homologous, depending on one's desired end. It would have been obvious to introduce the oxox gene of Hartman et al. and the ALS gene of Bernasconi et al. One would have been motivated to introduce these genes into the plants, given the obvious desirable properties of resistance to sclerotinia and herbicides, respectively, conferred by these genes. It was also obvious that the gene of interest could have been one that inhibits the production of a homologous protein. For example, the gene of interest could have been the sequence that expresses RNA that is antisense to the transcript of stearoyl-ACP desaturase in sunflower, to increase the production of stearate, as taught by Bidney et al. One would have been motivated to express such an RNA and increase the concentration of stearate production in sunflower oil, given the advantages asserted by Bidney et al. It also would have been obvious to produce progeny of the transgenic plants, for the purpose of propagation.

Applicants argue that Curtis et al. and Grayburn et al. teach transformation protocols for lettuce or sunflower, and neither describe or suggest using the ACT2 gene promoter to control transgenic expression in Compositae plants (response, paragraph bridging pages 5-6). However,

it is not necessary that a reference actually suggest changes or possible improvements that Applicants made. See *In re Sheckler*, 438 F.2d 999, 1001, 168 USPQ 716, 717 (CCPA 1971). Further, the references do not teach that only the very transgenes and promoters disclosed therein can be used with the transformation methods. Applicants also argue that Grayburn shows that "only" 5 of 10 T2 plants showed GUS expression (response, paragraph bridging pages 5-6). However, the claims do not encompass any limitation regarding the percentage of T2 generation plants showing transgene expression. See *In re Lindner*, 173 USPQ 356 (CCPA 1972) and *In re Grasselli*, 218 USPQ 769 (Fed. Cir. 1983) which teach that the evidence of nonobviousness should be commensurate with the scope of the claims. Applicants argue that An et al. do not suggest using the ACT2 gene promoter to control expression in Compositae plants or to obtain stable gene expression in progeny Compositae plants (response, page 6, 1st full paragraph). However, An et al. do suggest, based on high GUS expression levels obtained with the Arabidopsis ACT2 promoter-GUS constructs, that the ACT2 5'region is ideal for directing high-level expression of various transgenes in plants (page 117). This assertion is not limited to Arabidopsis plants. It is not necessary for a reference to actually suggest changes that Applicant made. See *In re Sheckler, supra.*

Applicants also argue that Hartman et al., Bernasconi et al., and Bidney et al. do not suggest using the ACT2 gene promoter to control expression in Compositae plants or to obtain stable gene expression in progeny Compositae plants (response, page 6, 2nd and 3rd full paragraphs and page 7, 1st full paragraph). However, Hartman et al. was cited for its teaching of the oxox gene, and the desirable property of conferring resistance to sclerotinia when expressed in transgenic plants, required for claims 12, 16, and 20. Bernasconi et al. was cited for teaching

herbicide tolerance genes, limitations recited claims 11 and 21. Bidney et al. was cited to address the claims directed towards inhibiting production of a homologous production.

Applicants also argue that Curtis et al., Hartman et al., and Bernasconi et al. teach away from the invention by using or recommending the CaMV 35S promoter (response, page 7, 2nd full paragraph). Again, Curtis et al. teach a method for lettuce transformation. There is nothing in Curtis to suggest that the method can only be practiced with the CaMV 35S promoter, or that it was vital to the transformation protocol. Page 21, lines 25-26 of Hartman et al., cited by Applicants, cites the CaMV 35S promoter as an example. Hartman et al. do not say that this is the only promoter that may be used, and state in the same paragraph cited by Applicants that the promoters that can be used include those that are active in a wide range of tissues (page 21, lines 21-24). An et al. teach that the ACT2 promoter is active in most plant organs (page 117). Column 4, lines 50-53 of Bernasconi et al. only indicates what suitable promoters are. The reference does not limit the promoter to be CaMV 35S.

Summary

8. Claims 1, 3-7, 9-14, 16, and 18-21 remain rejected.

Contact Information

Any inquiry concerning this or earlier communications from the Examiner should be directed to Ashwin Mehta, whose telephone number is 571-272-0803. The Examiner can normally be reached from 8:00 A.M to 5:30 P.M. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Amy Nelson, can be reached at 571-272-0804. The fax phone numbers for the organization where this application or proceeding is assigned are 571-273-8300. Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is

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July 20, 2005

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